



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

AUG 29 2000

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Ms. Chuxuan Ta
President
Princess Lifestyles
1286 South Garfield
Alhambra, CA 91720

W/L 76-00

Dear Ms. Ta:

This letter is in reference to your firm's repacking and marketing of "Sanalyn":

The labeling for "Sanalyn", including the carton containing the blister pack tablets and the brochure, make such claims as: "...relief of vaginal discomfort, itching, and menstrual cramps...helps to...improve overall gynecological health..." (carton); "...Princess Lifestyle Corp., now introduces SanalynTM as a way to enhance the immune system's defenses against infections and cancerous growths. The natural herbal formula in SanalynTM is specially designed to help prevent diseases of the female reproductive organs...enhances the metabolism of the vaginal muscle, improves blood circulation...thereby reduce the risk of infection...can also help to reduce excess leukorrheal discharge..." (brochure). The carton declares the ingredients and amounts per 500 mg. tablet as Rutaceae 60 mg., Labiatae 60 mg., Ranunculaceae 140 mg., Polygonaceae 60 mg., Compositae 60 mg., Resina Olibani 60 mg., and Sepiidae 60 mg. "Sanalyn" is therefore a drug within the meaning of section 201(g) of the Federal Food, Drug, and Cosmetic Act (Act). It is also a new drug as defined in section 201(p) of the Act because it is not generally recognized by experts to be safe and effective based on its formulation and labeling.

"Sanalyn" is a new drug without an approved new drug application (NDA) and may not be legally marketed in the United States (section 505(a) of the Act). The product is also misbranded (Section 502(f)(1) and (2) of the Act) because it fails to bear adequate directions for use and warnings against unsafe use for the indications in the labeling. "Sanalyn" is further misbranded (section 502(a) of the Act) because the labeling is misleading in that the product is not generally recognized as safe and effective as formulated and labeled. The carton declares Princess Lifestyle Corp. LLC to be the manufacturer of "Sanalyn", when in fact you are only the repacker and distributor

(marketer). Therefore, "Sanalyn" is in violation of regulation Title 21 Code of Federal Regulations [21 CFR 201.1] and further misbranded (section 502(a) of the Act).

This letter is not intended to be an all-inclusive review of your firm's products, product labeling and promotional materials. It is your responsibility to assure that all products marketed by your firm are in compliance with the Act and regulations.

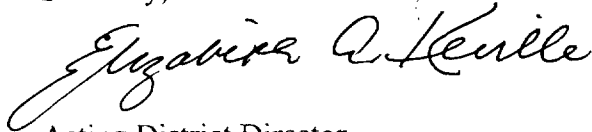
We request that you take prompt action to correct these violations. Failure to make prompt corrections may result in enforcement action being initiated by the Food and Drug Administration. This could include seizure of illegal products and injunctions against the manufacturer and/or distributor of the illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter describing the specific steps that you have taken to correct the violations and to prevent their recurrence. If corrective action cannot be completed within the fifteen (15) working days, state the reasons for the delay and the time within which corrections will be completed.

Your written response should be directed to the attention of:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612

Sincerely,



Acting District Director

cc: Mr. Minh (John) Ta, Vice President

California Department of Health Services, Food & Drug Branch
601 N. 7th Street
Sacramento, California 94234-7320
Attn: Stuart Richardson, Jr., Chief